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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of: C. ADAMS ET AL.

For: RECOMBINANT DNASE B DERIVED FROM STREPTOCOCCUS PYOGENES

Docket No.: 30429.39US02  
Filed: June 7, 1995  
Examiner: S. Walsh

Serial No.: 08/482,785  
Due Date: n/a  
Group Art Unit: 1814

BOX NON-FEE  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

- \* Transmittal Sheet, in duplicate, containing certificate under 37 CFR 1.8.^
- \_ A certified copy of a \_ application, Serial No. \_, filed \_, 199\_, the right of priority of which is claimed under 35 U.S.C. 119.^
- \_ Small entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by verified statement previously submitted.^
- \_ A verified statement to establish small entity status under 37 C.F.R. 1.9 and 1.27.^
- \_ A signed Combined Declaration and Power of Attorney.^
- \_ An Assignment of the invention to \_ and Recordation Form Cover Sheet.^
- \_ A Request for Extension of Time for \_ months and fee of \$\_.^
- \_ A check in the amount of \$\_, for \_.^
- \* A return postcard.^
- \* Other: Information Disclosure Statement w/form PTO-1449 and references.^
- \_ Amendment^ \_ No Additional fee is required^ \_ The fee has been calculated as shown:

CLAIMS AS AMENDED					SMALL ENTITY		or	OTHER	
	(1) CLAIMS REMAINING AFTER AMENDMENT	# # #	(2) HIGHEST NUMBER PREVIOUSLY PAID FOR	(3) PRESENT EXTRA	RATE	ADD'L FEE		RATE	ADD'L FEE
TOTAL CLAIMS		-	=		x 11 =	\$	or	x 22 =	\$
INDEPENDENT CLAIMS		-	=		x 39 =	\$	or	x 78 =	\$
( ) FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM					+125 =	\$	or	+ 250 =	\$
TOTAL					\$			\$	

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-2724.

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on this 3rd day of November, 1995.

MERCHANT, GOULD, SMITH, EDELL, WELTER & SCHMIDT  
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By: Michael B. Farber  
Name: Michael B. Farber  
Reg. No.: 32,612  
MBF/mrj

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(GENERAL)



30429.39US02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: ) Group Art Unit: 1814  
C. Adams et al. )  
 ) Examiner: S. Walsh  
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Serial No.: 08/482,785 )  
 ) Date Mailed:  
Filed: June 7, 1995 ) November 3, 1995  
 )  
For: RECOMBINANT DNASE B )  
DERIVED FROM ) Los Angeles,  
STREPTOCOCCUS PYOGENES ) California  
 )

#8  
B.83  
2/9/96

INFORMATION DISCLOSURE STATEMENT

Honorable Assistant Commissioner  
of Patents  
Washington, D.C. 20231

Gentlemen:

This document is an Information Disclosure Statement to  
the above-cited patent application.

Attached hereto is at least one Form PTO-1449 listing  
documents believed relevant to the subject application. The  
submission of the following information is not intended, nor  
should it be construed, to constitute an admission that any  
patent, article, or other information referred to herein is  
"prior art" unless specifically designated as such. In  
accordance with 37 C.F.R. § 1.97(b) the filing of this  
information shall not be construed to mean that a search has been

made or that no other material information may exist. Neither should its submission be construed to indicate that a thorough search should not be conducted by the Examiner.

It is believed that this disclosure complies with the requirements of 37 C.F.R. § 1.56, § 1.97, and § 1.98 and the Manual of Patent Examining Procedures § 707.05(b). If for some reason the Examiner considers otherwise, it is respectfully requested that the undersigned be telephoned so that any deficiencies can be remedied.

This Information Disclosure Statement is being submitted before the mailing date of a first Office Action on the merits. If an Office Action on the merits has in fact been mailed prior to the submission of this Information Disclosure Statement, authorization is hereby given to charge the required fee of \$220.00 pursuant to 37 C.F.R. § 1.17(p) to Deposit Account No. 13-2724.

These documents are not necessarily analogous art. Additionally, the order of the following documents is to be accorded no particular import as the order thereof is completely fortuitous.

It is respectfully requested that these documents be:

(1) fully considered by the Patent and Trademark Office during the examination of this application; and (2) represented on any patent which may issue on the application. Applicants respectfully request that copies of the PTO-1449 forms, as considered and initialled by the Examiner, be returned with the next communication.

Pursuant to 37 C.F.R. § 1.98(d), copies of the cited references for Exhibits 1-10 are not included with this Information Disclosure Statement. Exhibits 1-10 cited herein were previously made of record by the Patent and Trademark Office in the parent of this divisional application, Application Serial No. 08/393,889, filed February 24, 1995, or in its parent application, Application Serial No. 08/082,045, filed June 23, 1993. The parent applications are relied on for an earlier effective filing date under 35 U.S.C. § 120, as required by 37 C.F.R. § 1.98(d).

For Exhibits 11-14, a copy of each document is enclosed. Some of the documents may have markings thereon. No significance is meant to be attached to the markings.

Exhibit 1 is U.S. Patent No. 5,055,395 to Toth, issued October 8, 1991.

Exhibit 2 is U.S. Patent No. 5,082,785 to Manning et al., issued January 21, 1992.

Exhibit 3 is U.S. Patent No. 4,503,035 to Pestka et al., issued March 5, 1985.

Exhibit 4 is European Patent Publication No. 0613947 by Yutsudo et al., published September 7, 1994. This document is supplied for information only, as it is not prior art to the above-identified application. September 7, 1994 is after the effective filing date of the above-identified patent application, June 23, 1993. Therefore, it is not prior art under 35 U.S.C. § 102(a) or (b).

Exhibit 5 is a publication, M.A. Gerber et al., "Enzyme-Linked Immunosorbent Assay of Antibodies in Human Sera to Streptococcal DNase B," J. Lab. Clin. Med. 95: 258-265 (1980).

Exhibit 6 is a publication, T. Yutsudo et al., "A New Type of Mitogenic Factor Produced by *Streptococcus pyogenes*," FEBS Lett. 308: 30-34 (1992).

Exhibit 7 is a publication, M. Iwasaki et al., "Cloning, Characterization and Overexpression of a *Streptococcus*

pyogenes Gene Encoding a New Type of Mitogenic Factor," FEBS Lett. 331: 187-192 (1993).

Exhibit 8 is a publication, J. Sambrook et al., "Molecular Cloning, A Laboratory Manual" (Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, 1989), chs. 11-12 and 17.

Exhibit 9 is a publication, J.M. Wozney, "Using Purified Protein to Clone Its Gene," Methods Enzymol. 182: 738-749 (1990).

Exhibit 10 is a publication, G. Sofer, "Chromatographic Removal of Pyrogens," Bio/Technology: 1035-1038 (1984).

Exhibit 11 is a publication, G.C. Klein & W.L. Jones, "Comparison of the Streptozyne Test with the Antistreptolysin O, Antideoxyribonuclease B, and Antihyaluronidase Tests," Appl. Microbiol. 21: 257-259 (1971).

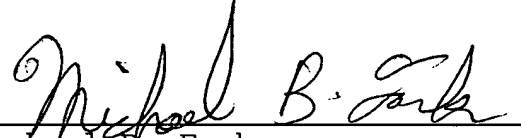
Exhibit 12 is a publication, S. Horinouchi et al., "A New Isolation Method of Plasmid Deoxyribonucleic Acid from *Staphylococcus aureus* Using a Lytic Enzyme of *Achromobacter lyticus*," Agric. Biol. Chem. 41: 2487-2489 (1977).

Exhibit 13 is a publication, R.A. Young & R.W. Davis,  
"Efficient Isolation of Genes by Using Antibody Probes," Proc.  
Natl. Acad. Sci. USA 80: 1194-1198 (1983).

Exhibit 14 is a publication, J.E. Mott et al.,  
"Maximizing Gene Expression from Plasmid Vectors Containing the  $\lambda$   
 $P_L$  Promoter: Strategies for Overproducing Transcription  
Termination Factor  $\rho$ ," Proc. Natl. Acad. Sci. USA 82: 88-92  
(1985).

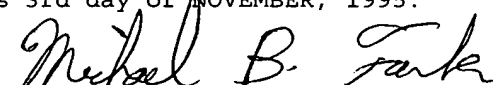
Respectfully submitted,

Date: November 3, 1995

  
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this paper,  
as described hereinabove, is being deposited in the United States Postal Service,  
as first class mail, in an envelope addressed to: Assistant Commissioner for  
Patents, Washington, D.C. 20231, on this 3rd day of NOVEMBER, 1995.

By:   
Name: Michael B. Farber